

Message Text

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ORIGIN HEW-06

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TO AMEMBASSY NEW DELHI IMMEDIATE

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E.O. 11652:N/A

TAGS: TPHY, OSCI, TBIO, IN

SUBJECT: DHEW/PHS/NIH/SFCP AGREEMENT 01-024-N, COLLABO-
RATIVE NEUROLOGIC STUDIES (BACHHAWAT, MUKHERJEE, AUSTIN) -
OFFICIAL TRAVEL OF DR. JAMES AUSTIN

PASS TO ACTING SCIATT TERISTA SCHAFER

REFERENCE: A)NEW DELHI 3014; B)STATE 239327; C)LETTERS
DATED SEPTEMBER 28, 1977 TO DRS. BACHHAWAT AND MUKHERJEE
AND SEPTEMBER 29, 1977 TO DR. J. H. AUSTIN

1. EMBASSY ADVISED DR. JAMES AUSTIN, PROFESSOR AND CHAIR-
MAN, DEPARTMENT OF NEUROLOGY, UNIVERSITY OF COLORADO,
PROJECT OFFICER SUBJECT AGREEMENT, WILL TRAVEL TO INDIA.
HE WILL CONSULT WITH DRS. BACHHAWAT AND MUKHERJEE IN
CALCUTTA AND, IF POSSIBLE AND NECESSARY, WITH DR. GOPALAN.

2. NIH CONCURS IN EMBASSY OPINION EXPRESSED IN REFTEL A
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THAT DEFINITIVE ACTION SHOULD BE TAKEN ON SUBJECT PROPOSAL.
ALTHOUGH NIH WAS NOT AWARE OF CORRESPONDENCE BETWEEN DR.
GOPALAN, ICMR, AND DR. AUSTIN, NIH RECOGNIZES GOPALAN'S AS
WELL AS THE EMBASSY'S NEED FOR INFORMATION ABOUT THE
OBJECTIVES OF DR. AUSTIN'S TRIP. IT IS ALSO ESSENTIAL
THAT THERE BE AN UNDERSTANDING AMONG THE PRINCIPALS

CONCERNED WITH THIS PROPOSAL, NAMELY, NIH, DR. GOPALAN,
DR. AUSTIN AND THE EMBASSY, AS TO THE PARAMETERS OF THE
DISCUSSION.

3. REFTTEL B AND REFTELS C WERE PREPARED IN RESPONSE TO REQUESTS TO NIH FROM THE EMBASSY, THE INDIAN RESEARCHERS, AND DR. AUSTIN FOR A DETAILED CITATION OF SPECIFIC DEFICIENCIES IN THE ICMR VERSION OF THE PROPOSAL AND THE INFORMATION NEEDED TO CORRECT THESE DEFICIENCIES AND DETERMINE COMPLIANCE WITH DHEW REGULATIONS ABOUT PROTECTION OF HUMAN SUBJECTS AND USE OF ABORTED FETAL TISSUE. IN ADDITION A GRATUITOUS ASSESSMENT WAS GIVEN OF FACTORS MITIGATING AGAINST ULTIMATE APPROVAL. NIH DID NOT INTEND TO CIRCUMVENT THE ICMR BY DEALING DIRECTLY WITH INDIAN RESEARCHERS. NIH, AS DID DR. AUSTIN, BELIEVED HIS INDIAN ASSOCIATES NEEDED A STATEMENT OF THESE ITEMS DIRECTLY FROM NIH FOR REASONS OF FAIRNESS AND TO ASSURE INFORMATION NEEDED WOULD NOT BE LOST THROUGH INTERPRETATION OR TRANSMISSION BY THE ICMR. THIS NIH OPINION WAS REINFORCED BY THE UNSATISFACTORY ASSURANCE SUBMITTED BY THE ICMR.

4. THE EMBASSY IS REQUESTED TO INFORM DR. GOPALAN AND OTHER APPROPRIATE OFFICIALS OF THE ICMR OF THE FOLLOWING NIH POSITION AND DECISION. THE SUBJECT PROPOSAL WAS SUBMITTED IN APRIL 1971. IT IS UNREALISTIC TO ASSUME THAT A RESEARCH PROPOSAL ACTUALLY WRITTEN MORE THAN SEVEN YEARS UNCLASSIFIED

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AGO IS STILL TECHNICALLY CURRENT, AND GIVES CONSIDERATION TO ADVANCES OCCURRING DURING THIS INTERIM IN THE FIELD OF RESEARCH PROPOSED, TO THE EXTENT THAT IT IS AMENABLE TO REVISION AS OFFERED IN NIH LETTER TO THE PRINCIPALS OCTOBER 1977 TO WHICH NO RESPONSE WAS RECEIVED. SUCH A PATCHWORK PROPOSAL, PARTICULARLY SINCE THE PRINCIPALS ARE NO LONGER AT THE INSTITUTE FROM WHICH THE APPLICATIONS WERE SUBMITTED, CANNOT REPEAT CANNOT, BE ACCEPTED BY NIH REGARDLESS OF ITS CONFORMANCE TO RECENT DHEW REGULATIONS ON PROTECTION OF HUMAN SUBJECTS AND USE OF ABORTED FETAL TISSUE AND THE REGULATION ISSUED JANUARY 13, 1978 APPLICABLE TO RESEARCH INVOLVING CHILDREN. THERE ARE NO COPIES OF THE VERSION OF THE PROPOSAL ORIGINALLY REVIEWED BY NIH PENDING BEFORE THE ICMR. THE ICMR RETURNED THESE TO THE EMBASSY WHICH RETURNED THEM TO NIH.

5. EMBASSY IS ALSO REQUESTED TO INFORM DR. GOPALAN THAT THE NIH OFFERS THE FOLLOWING TWO ALTERNATIVES: FIRST, THE PRINCIPAL INVESTIGATORS, DRS. BACHHAWAT AND MUKHERJEE, ARE INVITED TO SUBMIT TO NIH THROUGH THE ICMR A COMPLETELY NEW RESEARCH PROPOSAL FOR COMPLETE REVIEW BY NIH. THE PROPOSAL MUST INCLUDE SUFFICIENT DETAIL TO PERMIT AN EVALUATION OF TECHNICAL MERIT AND RELEVANCE TO PRESENT PROGRAM

PRIORITIES OF NIH. IN ADDITION, IT SHOULD PERMIT A DETERMINATION AS TO WHETHER THE RESEARCH IS IN CONFORMANCE WITH DHEW REGULATIONS APPLICABLE TO A) PROTECTION OF HUMAN

SUBJECTS, B) RESEARCH AND RELATED ACTIVITIES INVOLVING FETUSES, PREGNANT WOMEN AND HUMAN IN VITRO FERTILIZATION, AND C) THE RECENT RECOMMENDATION PERTAINING TO RESEARCH INVOLVING CHILDREN ISSUED IN THE FEDERAL REGISTER, JANUARY 13, 1978. THE NEW RESEARCH PROPOSAL MUST BE ACCOMPANIED BY PROPERLY DOCUMENTED "SPECIAL ASSURANCE OF PROTECTION OF HUMAN SUBJECTS" INCLUDING A RECORD OF THE ESTABLISHMENT AND MEMBERSHIP OF AN INSTITUTIONAL REVIEW BOARD AND AN EXPLANATION OF HOW AN "INFORMED CONSENT" WILL BE OBTAINED.

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6. SECOND, ICMR WITHDRAW PROPOSAL FROM CONSIDERATION FOR NIH SUPPORT OF SUBJECT PROJECT AND PROVIDE UNILATERAL SUPPORT WITH ICMR FUNDS AS HAS BEEN DONE IN THE CASE OF STROKE STUDY AND SIX OTHER DHEW PROJECTS IN WHICH NIH HAS HAD AN INTEREST AND CONTRIBUTED FUNDS AND/OR TECHNICAL CONSULTATION OVER A PERIOD OF YEARS. IF ICMR ELECTS THIS OPTION, IN VIEW OF DR. AUSTIN'S LONG AND DEDICATED INTEREST IN HIS INDIAN ASSOCIATE, IT IS RECOMMENDED THAT THE EMBASSY NEGOTIATE WITH THE ICMR TO PROVIDE AN OPPORTUNITY FOR DR. AUSTIN TO MAINTAIN SOME FORM OF COLLABORATION WITH THEM AND TO HAVE ACCESS TO THE RESULTS OF THEIR STUDIES AS GOPALAN AGREED TO, AND AS WAS REPORTED IN HEALTH PANEL C, ANNEX V OF MINUTES OF THE U.S.-INDIAN SUBCOMMITTEES ON SCIENCE AND TECHNOLOGY. ANY NIH ENDORSEMENT OR SUPPORT OF THIS FORM OF COLLABORATION, SUCH AS PROVIDING TRAVEL FUNDS, WOULD OF COURSE ALSO DEPEND UPON THE PROJECT'S SATISFYING DHEW REGULATION CONCERNING PROTECTION OF HUMAN SUBJECTS.

7. THE EMBASSY SHOULD INFORM GOPALAN THAT THE OVERALL OBJECTIVES OF DR. AUSTIN'S VISIT ARE TO DISCUSS THE STATUS OF THE PROPOSED RESEARCH COLLABORATION WITH DR. BACHHAWAT AND DR. MUKHERJEE, AND IF POSSIBLE, WITH DR. GOPALAN, TO DETERMINE WHAT CAN BE DONE WITHIN THE PARAMETERS OF THE NIH DECISION AND OPTIONS GIVEN ABOVE, AND THOSE OF THE INDIAN INVESTIGATORS AND THE ICMR, TO OBTAIN FINANCIAL SUPPORT FOR HIS INDIAN ASSOCIATES AND RE-ESTABLISH AN ACTIVE SCIENTIFIC COLLABORATION SUCH AS HAS PREVAILED IN THE PAST. SPECIFICALLY, DR. AUSTIN WILL: 1) REVIEW THE CURRENT RESEARCH INTERESTS AND OPPORTUNITIES OF DR. BACHHAWAT AND DR. MUKHERJEE AND IDENTIFY MUTUAL INTERESTS. 2) MEET THE PROFESSIONAL ASSOCIATES OF HIS ACQUAINTANCES

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AND PAST COLLABORATORS AT THEIR RESPECTIVE INSTITUTIONS, ASSESS THE CONDUCIVENESS OF THE ACADEMIC ENVIRONMENT TO RESEARCH, AND EVALUATE AVAILABLE RESEARCH FACILITIES.

3) THROUGH DISCUSSIONS WITH DR. BACHHAWAT AND DR. MUKHER-

JEE, AND IF NECESSARY AND POSSIBLE, WITH DR. GOPALAN, DETERMINE WHETHER STUDIES CONTROVERSIAL, OR ILLEGAL, IN THE U.S. CAN BE DROPPED FROM THE STUDY AND A COMPLETELY NEW RESEARCH PROPOSAL PREPARED AND SUBMITTED TO NIH FOR REVIEW WITH NECESSARY DOCUMENTS ON PROTECTION OF HUMAN SUBJECTS. 4) IF THE ICMR WILL AGREE TO SUBMIT A NEW RESEARCH PROPOSAL TO NIH, DR. AUSTIN WILL ASSIST HIS INDIAN COLLABORATORS IN PREPARING PROJECT DESCRIPTIONS FOR NIH ASSESSMENT OF TECHNICAL MERIT. HE WILL ALSO REVIEW FOR THE INDIAN SCIENTISTS AND ICMR, IF DESIRED, THE EVOLUTION OF U.S. MEASURES FOR THE PROTECTION OF SUBJECTS IN CLINICAL INVESTIGATIONS AND, IF NEEDED, PROVIDE GUIDANCE IN THE PREPARATION OF A SPECIAL ASSURANCE, INCLUDING ESTABLISHMENT OF AN INSTITUTIONAL REVIEW BOARD AND OBTAINING INFORMED CONSENT.

8. THE REGULATIONS CONCERNING THE MATTERS REFERRED TO IN ITEM 4 ABOVE ARE SET FORTH IN THE EXCERPT SENT TO DRS. BACHHAWAT, MUKHERJEE, AND AUSTIN, REFLECTS C, AND THE EMBASSY FROM THE CODE OF FEDERAL REGULATIONS 45, CFR 46, PROTECTION OF HUMAN SUBJECTS REVISED APRIL 1, 1977, SUBPART A, PARAGRAPHS: 46.101, APPLICABILITY; 46.103, DEFINITIONS; 46.106, MINIMUM REQUIREMENTS FOR GENERAL ASSURANCE (WHICH DESCRIBES THE INSTITUTIONAL REVIEW BOARD); 46.107, MINIMUM REQUIREMENTS FOR SPECIAL ASSURANCE (THIS IS TYPE OF ASSURANCE REQUIRED FOR THIS OR OTHER INDIAN PROJECTS); 46.110 DOCUMENTATION OF INFORMED CONSENT. SUBPART B PERTAINING TO FETUSES AND PREGNANT WOMEN PARAGRAPHS: 46.203, DEFINITIONS; 46.206, GENERAL LIMITATIONS; 46.207, ACTIVITIES DIRECTED TOWARD PREGNANT WOMEN AS SUBJECTS; 46.209, ACTIVITIES DIRECTED TOWARD FETUSES EX UTERO
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INCLUDING NON-VIABLE FETUSES AS SUBJECTS; 46.210, ACTIVITIES INVOLVING THE DEAD FETUS, FETAL MATERIAL OR THE PLACENTA. THE EMBASSY MAY ALSO WISH TO REVIEW THESE FOR DR. GOPALAN AND AGAIN REITERATE THE IMPORTANCE OF THESE MATTERS. NIH RECENTLY HELD TWO INTERNATIONAL CONFERENCES DEALING WITH VARIOUS ASPECTS OF THESE TOPICS. THE FIRST ONE DEALING WITH CLINICAL TRIALS WAS ATTENDED BY 600 PEOPLE FROM THE U.S. AND ABROAD WHO BELIEVED IT SUFFICIENTLY IMPORTANT TO PAY THEIR OWN WAY TO THE MEETING.

9. ANY ASSISTANCE THAT THE EMBASSY CAN PROVIDE DR. AUSTIN WILL BE GREATLY APPRECIATED. HE SPENT A SABBATICAL IN INDIA SOME YEARS AGO AS INDICATED ABOVE, HE HAS BEEN AN ACTIVE AND DEDICATED PROPONENT OF THE PRINCIPAL INVESTIGATOR OVER A LONG PERIOD OF TIME. HE HAS A STRONG EMPATHY FOR THE NEEDS OF HIS COLLABORATOR AND INDIAN SCIENTISTS IN GENERAL. IT IS UNFORTUNATE THAT HIS INTEREST AND CAPABILITY WERE NOT UTILIZED IN THE CONTINUATION OF THIS

COLLABORATION TERMINATED BY THE ICMR MARCH 31, 1972.

10. ETA NEW DELHI APRIL 15, 1978 FROM HONG KONG VIA
CATHAY PACIFIC AIRWAYS. ETD FROM CALCUTTA ON APRIL 22,
1978. DR. AUSTIN HAS MADE ARRANGEMENTS FOR HOTEL ACCOM-
MODATIONS.

11. USDO AUTHORIZED ADVANCE PER DIEM AND MISCELLANEOUS
EXPENSES.

12. FISCAL DATA: TO N-003024, APPROPRIATION 75X1102,
ALLOTMENT 8-A731801; 01003024/OD, 21.2Z.

13. NIH REQUESTS CONCURRENCE OR NOTIFICATION IF TRIP IS
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INAPPROPRIATE. CHRISTOPHER

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